layer; and wherein the membrane has a thickness of 0.5 mm to 2.0 mm.

REMARKS

Claim 1 has been amended to delete the embodiment of the invention wherein the suturable adhesion-preventing membrane for guided tissue regeneration comprises at least one non-woven fabric layer made of collagen fibers and a coating layer of gelatin or hyaluronic acid provided on a surface of the membrane.

Claim 15 has been amended to correct the range of bulk density of the compressed non-woven fabric layer composed of cross-linked collagen fibers. The range of bulk density recited in amended claim 15, i.e., 1.0×10^{-3} to 2.0 g/cm^3, is supported in the specification disclosure on page 15, line 12.

Reconsideration of the 35 U.S.C. § 103(a) rejection of claims 1-33 as being obvious in view of Light et al., U.S. Patent No. 5,514,181 (hereinafter: Light) is respectfully requested for the reasons explained below.

The distinctions between the suturable adhesion-preventing membrane for guided tissue regeneration of the present invention as

recited in amended claim 1, the broadest claim of the application, and the absorbable prosthesis of Light, are explained in light of the table below.

The suturable adhesion-preventing membrane for guided tissue regeneration of the present invention as recited in amended claim 1 comprises (1) at least one non-woven fabric layer made of collagen fibers and (2) at least one sponge layer made of collagen and is further characterized in that a surface of the membrane is provided with (3) a coating layer of gelatin or hyaluronic acid.

The prosthesis of Light, on the other hand, comprises a layer of a synthetic bioabsorbable material (Col. 2, lines 47-48 and 62-63, and Col. 6, lines 27-28); a bioabsorbable film layer (Col. 2, line 49, and Col. 6, line 28) and a layer of a bioabsorbable sponge (Col. 2, line 50, and Col. 6, lines 28-29).

The suturable adhesion-preventing membrane for guided tissue regeneration of the present invention as recited in amended claim 1 and the relevant teachings of Light are compared in the table below.

Present Invention	Light
Coating layer of	2: Forminous layer, Synthetic bioabsorbable materials **(column 2, lines 62-63; column 6, lines 27-28)** a polymer or copolymer of lactic acid or glycolic acid, oxidized regenerated cellulose, polydioxanone (PDS), a copolymer of lactic acid and ε-caprolactam, polyhydroxybutyric acid or a copolymer of hydroxybutyric acid and hydroxyvaleric acid. **(column 3, lines 1-5)** 2 is composed of a polylactide/polyglycolide mesh (column 6, line 30)
gelatin or hyaluronic acid (a)	------
Non-woven fabric layer made of collagen fibers (b)	bioabsorbable film formed by drying an aqueous solution or suspension comprising biopolymer such as, collagen, a glycosaminoglycan, such as hyaluronic acid, or the like **(column 3, lines 28-31)** 3 is composed of Type I collagen fibers cross-linked with hexamethylene diisocyanate **(column 6, lines 31-32)**

Sponge layer made of collagen (c)	bioabsorbable biopolymer sponge **(column 3, line 57)** the sponge comprises collagen, a glycosaminoglycan such as chondroitin sulfate or hyaluronic acid or a mixture of such biopolymers **(column 3, lines 63-65)** 4 is also formed from Type I collagen fibers cross linked with hexamethylene diisocyanate **(column 6, lines 33-35)**

Applicant, in the response filed March 18, 2002, to the first action, explained that the foraminous layer of the structure of Light is required to be composed of synthetic bioabsorbable materials. However, in the present [final] action, the Examiner has taken the position that Light does not require the foraminous layer to be a synthetic material.

The Examiner is respectfully requested to reconsider his position. Light unequivocally describes the foraminous layer as being a synthetic bioabsorbable material. Specifically, in Col. 2, lines 48-50, Light describes that his invention provides "a bioabsorbable ligament or tendon prosthesis in the form of a multilayered spiral roll comprising the following spiral layers: a foraminous layer of a synthetic bioabsorbable material; a

bioabsorbable film, and a layer of a bioabsorbable sponge." (Emphasis added). In Col. 2, lines 62-64, Light describes the "chief function of the foraminous layer of a synthetic bioabsorbable material" as being to provide tensile strength to the prosthesis. (Emphasis added). In Col. 6, lines 66-67, Light again characterizes the ligament or tendon "according to the present invention" as comprising separate layers of foraminous synthetic bioabsorbable material, bioabsorbable film and bioabsorbable sponge. Nowhere does Light describe the foraminous layer as simply a foraminous bioabsorbable layer or as being preferably of a synthetic bioabsorbable material. The foraminous layer is described and claimed only as being a synthetic bioabsorbable material.

The Examiner cites the description of preferred materials of the foraminous layer in Col. 3, lines 1-11, as supporting his position that the foraminous layer is not required to be a synthetic material. The action notes that the passage in Col. 3, lines 1-11, does not state that the material must be synthetic. However, in light of the clear descriptions elsewhere in Light of the foraminous layer being a synthetic bioabsorbable material, the

description of preferred materials in Col. 3 need not state that the material must be synthetic. Moreover, it is noted that the description in Col. 3 also does not state or imply that the material can be other than a synthetic material.

If the Examiner maintains his position, he is respectfully requested to explain how the description of the invention in Col. 2, lines 48-50, of Light as being a bioabsorbable ligament or tendon prosthesis in the form of a multilayered spiral roll comprising a foraminous layer "of a synthetic bioabsorbable material" can mean that the foraminous layer is not [necessarily] of a synthetic bioabsorbable material.

The description in Col. 4, lines 64-66, is also not inconsistent with and does not rebut the requirement for the foraminous layer to be of a synthetic bioabsorbable material. The only possible interpretation of the description in Col. 4, lines 64-66, of Light, when considered in light of the descriptions in Light noted above of its invention, is that the bioabsorbable film can be a synthetic bioabsorbable material.

Applicant explained in the first response that it is improper for the Examiner to take the position that the device of Light can

be modified by substituting a non-woven layer of collagen for the synthetic layer. It is well-established that a patent cannot be properly modified where the modification will destroy the invention on which the patent is based. See *Ex parte Hartmann*, 186 USPQ 366 (Bd. App. 1974). Thus, a proposed modification of Light to substitute a collagen layer for the foraminous layer of a synthetic bioabsorbable material is also improper.

Notwithstanding that the foraminous layer of Light is required to be of a synthetic bioabsorbable material, even if it is assumed for the sake of argument that the foraminous layer can be made of collagen, the resultant structure of Light will not be a combination of (1) at least one non-woven fabric layer made of collagen fibers and (2) at least one sponge layer made of collagen and (3) a coating layer of gelatin or hyaluronic acid. Please refer to the table above.

Regarding claims 15-33, the Examiner has not explained in the final rejection where or how Light supports the obviousness of a membrane structure where each surface of the membrane is coated with a layer containing gelatin or hyaluronic acid as recited in independent claims 15, 16, 32 and 33 of this application. If the

final rejection is maintained, the Examiner is requested to explain the support in Light (or other prior art) for the rejection of claims 15, 16, 32 and 33.

Finally, it is noted that the structure of Light is in the form of a multilayer spiral roll and is used for repair of damaged ligaments and/or tendons. On the other hand, the subject matter of the present invention is directed to a suturable adhesion-preventing membrane. The prosthesis of Light does not require and is insufficient to suggest the properties and composition of the layers of a suturable adhesion-preventing membrane.

Removal of the 35 U.S.C. § 103(a) rejection of claims 1-33 is in order and is respectfully requested.

The foregoing is believed to be a complete and proper response to the Office Action dated May 29, 2002, and is believed to place this application in condition for allowance. If, however, minor issues remain that can be resolved by means of a telephone interview, the Examiner is respectfully requested to contact the undersigned attorney at the telephone number indicated below.

PATENT APPLN. NO. 09/489,473
RESPONSE UNDER 37 C.F.R. § 1.116

PATENT
FINAL

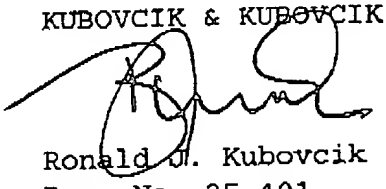
Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attachment is captioned "VERSION WITH MARKINGS TO SHOW CHANGES MADE."

In the event that this paper is not considered to be timely filed, applicant hereby petitions for an appropriate extension of time. The fee for any such extension may be charged to our Deposit Account No. 111833.

In the event any additional fees are required, please also charge our Deposit Account No. 111833.

Respectfully submitted,

KUBOVCIK & KUBOVCIK



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PATENT APPLN. NO. 09/489,473
RESPONSE UNDER 37 C.F.R. § 1.116

PATENT
FINAL

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

Claims 1 and 15 have been amended as follows:

1. **(Amended)** A suturable adhesion-preventing membrane for guided tissue regeneration comprising [~~at least one non-woven fabric layer made of collagen fibers, or having~~] at least one non-woven fabric layer made of collagen fibers and at least one sponge layer made of collagen, characterized in that a surface of the membrane is provided with a coating layer of gelatin or hyaluronic acid.

15. **(Amended)** A suturable adhesion-preventing membrane for guided tissue regeneration comprising: a compressed non-woven fabric layer composed of cross-linked collagen fibers wherein the layer has fibers having a fiber diameter of 20 to 100 μm, a bulk density of 1.0×10^{-3} to [~~5.0×10^{-2} g/cm^3~~] **2.0 g/cm^3** and a thickness of 0.2mm to 1.0 mm; and a coating layer containing gelatin or hyaluronic acid covering each surface of the compressed collagen

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non-woven fabric layer; and wherein the membrane has a thickness of 0.5 mm to 2.0 mm.